November 25, 2022

Electronic submission sent through the Federal eRulemaking Portal

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-N-0862; RIN 0910-AH62

To Whom It May Concern:

We write to you as members of the Free the Pill coalition, a group operated by Ibis Reproductive Health that includes over 150 organizations and individuals who have been working since 2004 to build the evidence in support of over-the-counter oral contraceptives in the United States. We appreciate the opportunity to comment and provide feedback on the proposed rule on Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU). While we generally support the proposed rule, we ask that you take into consideration the following concerns when developing the final rule to ensure that it supports advancing equitable access to nonprescription products.

PART 314-Applications for FDA Approval to Market a New Drug

§314.56 Nonprescription drug product with an additional condition for nonprescription use (ACNU)

We are strongly supportive of measures to increase equitable access to safe and effective products by removing prescription barriers that are not medically necessary. Taking steps to allow simultaneous marketing of non-prescription drugs with an ACNU and comparable prescription drugs has the potential to expand access for many people and expand consumer choice. We are also supportive of the intent of the agency to keep the definition of ACNU "intentionally broad to give applicants flexibility regarding the types of additional conditions applicants may propose and how those conditions can be implemented." This flexibility is important for the applicant to be able to tailor ACNU to actual needs and to result in truly broader channels of access.

We also appreciate the proposed rule's clear requirements that any ACNU be closely linked to evidence that a label alone is insufficient. As described in the current proposed rule, "an ACNU will require both the applicant's demonstration and FDA determination that labeling alone is insufficient to ensure appropriate self-selection or appropriate actual use, or both." However, we also urge the FDA to specify that any ACNU imposed be narrowly tailored to impose minimal additional burden on consumers while still meeting the evidence-based needs for an ACNU. This is critical for the proposed rule to truly result in expanded access and to avoid inadvertently impeding access to medications that can be taken safely and effectively on a non-prescription basis.

Additionally, in the implementation of the proposed rule, we urge the FDA to work closely with applicants

to permit streamlined self-selection and label testing alongside potential ACNUs, in order to minimize the additional time and expense associated with multiple rounds of testing, which can delay access to non-prescription products that can safely and effectively be used with an ACNU.

§314.80 Other postmarketing reports

Under the proposed rule, the sponsor is required to report failures in the implementation of an ACNU to the FDA Adverse Event Reporting System (FAERS), whether or not the failure in implementation is associated with an adverse event. We are concerned that this requirement is overly broad, requiring clinically unnecessary reporting of events that are unrelated to the product's safety, effectiveness, or clinical impact, such as failures on the retailers' side which are out of the applicants' control and do not add to our understanding of the effectiveness of the ACNU. As the reporting requirement currently stands, we are concerned that this will both overburden the system and the applicant, detracting from actual consideration of adverse incidents which should be prioritized. We urge the agency to consider alternatives to the current reporting language, such as limiting FAERS reporting to adverse incidents events related to safety and effectiveness, including inappropriate use or self-selection, or consolidated reporting of failures that are unrelated to safety and effectiveness (such as a computer system failure). This would not impact the required reporting of a single individual case safety report (ICSR) in the case of an adverse event associated with a failure in implementation of an ACNU.

Free the Pill appreciates the opportunity to submit comments on this proposed rule. If you have any questions or require any additional information, please contact Victoria Nichols at Ibis Reproductive Health at vnichols@ibisreproductivehealth.org.

Sincerely,

Organizations
AAPI Youth Rising
Advocates for Youth
Advancing New Standards in Reproductive Health (ANSIRH)
Centering Equity, Race, and Cultural Literacy in Family Planning (CERCL-FP)
Center for Biological Diversity
CENTRS Health
Ibis Reproductive Health
Jane Fonda Center
National Birth Equity Collaborative
National Institute for Reproductive Health
National Latina Institute for Reproductive Justice
National Organization for Women
SisterLove, Inc
SisterReach TN & IL
Society for Maternal-Fetal Medicine
Society for Adolescent Health and Medicine (SAHM)
QueerDoc
Reproaction
Rhia Ventures

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